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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,987	09/09/2003	David E. Francischelli	P-10081.03	1294

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EXAMINER

VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/657,987

Applicant(s)

FRANCISCHELLI ET AL.

Examiner

Peter J. Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/3, 5/4.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-14 are pending. The action is non-final.

The application is a divisional of 10/132,379 now USPN 6,648,883. Claims 1-14 are the analogous system claims to the patented method claims.

The filing date is 4-26-01 due to provisional application 60/287,202.

Note: intended use language (ex. method steps such as initiating energy responsive to measured impedance) does not add structure to a claimed invention in system claims. The rejections below reflect this maxim. In order to acquire patentable weight from intended use claim language, the Applicant should insert claim language positively reciting structure (related to the intended use) not found in the prior art.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 1. Claims 7-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter**

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which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The **claimed** phrase “impedance measuring electrode” is not found in the specification. Although this deficiency does not necessarily preclude examination of claims 1-6 because the Examiner has **inferred** its meaning, claim 7 includes language toward a “second” impedance measuring electrode that is interconnected with a first impedance measuring electrode and a first and second ablation means. The specification is completely unhelpful in apprehension of claim 7. (Claims 8-14 depend upon claim 7). It is as the claims were written independently of the specification. The Applicant is advised to clarify, without adding new matter, where in the specification exists two ablation means and two impedance measuring electrodes. Upon doing this, more appropriate prior art will be applied by the Office for rejection.

Note: the Examiner merely did a computerized word search for “impedance measuring electrode” with the parent application’s patent (6,648,883) in addition to a visual skimming of the instant patent’s specification. In the event the term is in the instant application’s specification, the Applicant is advised to point it out.

2. Claims 4-6 are 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Applicant neglects to positively recite any new structure in these claims. “Detecting”, “initiating”, “employing”

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and "responding" as claimed are steps in a method and do not add any new structure to the invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 7-14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a *specific and substantial* asserted utility or a well established utility. The phrase "impedance measuring electrode" is not found in the specification.

Claims 7-14 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a *specific and substantial* asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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1. Claims 1-2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Nardella (5,713,896).

Independent claim 1

An ablation system (100, see figure 1), comprising:

generating means (106, 26) for generating ablation energy;

an ablation device (104, 10) comprising first ablation means (108) connectable to the generating means and locatable adjacent a first tissue site (102) to be ablated, for applying the generated ablation energy to the first tissue site;

a first impedance measuring electrode (112, col. 4:39-46) mounted to the ablation device (104) so that the first impedance measuring electrode (112) is adjacent the first tissue site (102) when the first ablating means (108) is adjacent the first tissue site;

impedance measurement circuitry (116, 26a) connectable to the first impedance measuring electrode to measure impedance at the first tissue site, using the first impedance measuring electrode (112, col. 4:39-46); and

control circuitry (118, 26a) operably coupled to the generating means to initiate and terminate the application of ablating energy to the first ablating means, wherein the control circuit is coupled to the impedance measurement circuit (see figure 3 where 26a and 26b rest adjacently) and terminates application of ablation energy to the first ablating means responsive to occurrence of an impedance plateau (implied by Nardella with the language, "power control means...for regulating the electrosurgical energy

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delivered to the living tissue...in response to the impedance signal *to maintain the tissue impedance within a preselected range*, " disclosed in column 10:39-45) measured by the impedance measuring circuitry using the first impedance measuring electrode (112), following initiation of application of ablating energy to the first ablating means (see patented claim 1, especially the last limitation).

Dependent claims (parentheticals refer to Nardella)

2. A system as in claim 1 wherein the first ablating means (108) is a first ablation electrode (108) and wherein the generating means comprises an R-F generator (106, figure 1).

4. A system as in claim 2 wherein the first ablation electrode is employed (intended use language) as the first impedance measuring electrode. (108 is capable of being used as an impedance measuring electrode – it is the analogue of 112, which is employed as an impedance measuring electrode.) Also note the circuit in figure 2, which discloses analogous electrodes 146 and 148.

2. Claims 1-2 and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Sherman (5,971,980).

Independent claim 1

An ablation system, comprising:

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generating means (50) for generating ablation energy;

an ablation device (10) comprising first ablation means (22,26) connectable to the generating means and locatable adjacent a first tissue site to be ablated, for applying the generated ablation energy to the first tissue site (col. 7:5-16);

a first impedance measuring electrode (col. 7:5-16, related to 78) mounted to the ablation device so that the first impedance measuring electrode is adjacent the first tissue site when the first ablating means is adjacent the first tissue site;

impedance measurement circuitry (52) connectable to the first impedance measuring electrode to measure impedance at the first tissue site, using the first impedance measuring electrode; and

control circuitry (52) operably coupled to the generating means to initiate and terminate the application of ablating energy to the first ablating means, wherein the control circuit is coupled to the impedance measurement circuit (processor 52 performs both impedance measuring and feedback control as disclosed in col. 7:9-13) and terminates (intended use) application of ablation energy to the first ablating means responsive to occurrence of (intended use) an impedance plateau (it can be argued that a "plateau" is reached at the moment a measured limit reaches outside a predetermined range/threshold as disclosed in patented claim 1) measured by the impedance measuring circuitry (52) using the first impedance measuring electrode, following (intended use language) initiation of application of ablating energy to the first ablating means.

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Dependent claims (parentheticals refer to Sherman)

2. Sherman discloses RF energy (col. 1: 55-58 and col. 3: 52) application via two ablating means / two RF electrodes (22 and 26).

4. A system as in claim 2 wherein the first ablation electrode is employed (intended use language) as the first impedance measuring electrode.

5,6. Sherman discloses monitoring by the processor (52) relative impedance changes (col. 7:5-23) (measured impedance over time) anticipating claims 5 and 6, which claim a processor (52). Detecting impedance plateaus and acceptable degree/rate of change is intended use language. These are merely steps in an ablation method. **There is no claimed structural difference** between the claimed processor and Sherman's processor (52).

Claim Rejections - 35 USC § 103

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman or Nardella in view of Chia et al. (5,913,856).

Sherman and Nardella neglect to disclose irrigated electrodes.

Chia et al. discloses, *inter alia*, an analogous RF ablation device that includes irrigated electrodes.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Sherman or Nardella in view of Chia et al. by including

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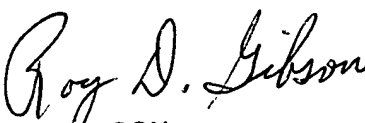
irrigated electrodes. The motivation would be to maintain a proper electrode temperature by a cooled fluid irrigation to partially compensate for the temperature rise due to RF energy delivery as posited in Chia et al. column 1 lines 62-67.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746 7013 for regular communications and 703 746 7013 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0858.

Pete Vrettakos
August 6, 2005


ROY D. GIBSON
PRIMARY EXAMINER